IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

ASTRAZENECA LP and ASTRAZENECA AB, Plaintiffs, v. APOTEX, INC. and APOTEX CORP., Defendants.	Civil No. 09-1518 (RMB) **SUPPLEMENTAL OPINION**

Appearances:

Attorneys for Plaintiffs
Andrew T. Berry, Esquire
Mark H. Anania, Esquire
McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07101-0652

Denise L. Loring, Esquire
Pablo D. Hendler, Esquire
Christopher J. Harnett, Esquire
Derek M. Kato, Esquire
Ropes & Gray, LLP
1251 Avenue of the Americas
New York, New York 10036

Attorneys for Defendants
Eric I. Abraham, Esquire
Hill Wallack, LLP
202 Carnegie Center
Princeton, New Jersey 08543

Richard J. Basile, Esquire
David W. Aldrich, Esquire
St. Onge Steward Johnson & Reens, LLC
986 Bedford Street
Stamford, Connecticut 06905

BUMB, United States District Judge:

On May 14, 2009, this Court issued an Opinion and Order [Dkt. Nos. 119, 120] concerning Plaintiffs' request for a preliminary injunction. Although the Court determined the vast majority of issues underlying Plaintiffs' request for relief, several issues surrounding the element of "specific intent" remained unresolved. The Court ordered Defendants to notify the Court by the end of the day on May 14, 2009, whether they wished to extend the TRO pursuant to Fed. R. Civ. P. 65(b)(2) so that the Court could continue the preliminary injunction hearing and resolve the issues relevant to specific intent. At the end of the day, Defendants advised the Court that they wanted to continue the hearing to allow the Court to decide these issues. Accordingly, on May 20, 2009, the Court continued the hearing.

As the Court set forth in its prior opinion, in order to obtain a preliminary injunction, AstraZeneca must prove a likelihood of success on the merits of its inducement claim. Part of this claim requires AstraZeneca to show that Apotex likely had the specific intent to cause infringement of AstraZeneca's patent. Specific intent "requires more than just intent to cause the acts that produce direct infringement. Beyond that threshold knowledge, the inducer must have an affirmative intent to cause direct infringement." DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1306 (Fed. Cir. 2006) (emphasis

added). "[I]nducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities." Id. However, "direct evidence [of intent] is not required; rather, circumstantial evidence may suffice." Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988), cert. denied, 488 U.S. 968 (1988).

Although both sides had initially presented evidence on the issue of specific intent, there were some key questions that remained unanswered. Specifically, there was no evidence in the record concerning Apotex's attempts to develop an alternative non-infringing label. Additionally, there was no evidence as to whether the FDA may have entertained any alternative label proposals. These questions were at the heart of the issue of Apotex's intent and, thus, critical to the Court's determination of that issue.

At the hearing, Apotex presented the testimony of Ms. Bernice Tau, the Director of Regulatory Affairs at Apotex, to address these questions. Ms. Tau testified that Apotex's label was a copy of AstraZeneca's label because it was required to be such by the FDA. (Tr., May 20, 2009 ("Tr.") at 5; see also 21 U.S.C. § 355(j)). She explained that, pursuant to the carve-out provision of Section viii, Apotex removed all references in its label to once daily dosing as best it could. (Tr. at 17-19). In

addition, she explained that, per the advise of counsel, Apotex added some language to its proposed label to emphasize "by administration twice-daily." (Id. at 19-21; see also Hearing Ex. D-16 at 9, 10, 12, 14). Ms. Tau stated that Apotex submitted its ANDA application with this additional language despite her own experience and understanding that the FDA does not permit additional language. (Tr. at 20). On March 2, 2007, Apotex received a Labeling Deficiencies letter from the FDA, which instructed Apotex to remove the additional text. (Id. at 22, 25; Hearing Ex. D-17 at APO 003051). Several days later, on March 14, 2007, the FDA sent Apotex another Labeling Deficiencies letter via fax, which included a "template" of the precise language that Apotex was directed to insert in its label. (Tr. at 23; Hearing Ex. D-17 at APO 003054). On November 6, 2007, Apotex submitted a Labeling Amendment to its ANDA based on the FDA Deficiency letters it had received. (Hearing Ex. D-17 at APO 003060). All changes requested by the FDA were incorporated into Apotex's final ANDA application.

Ms. Tau also testified that it was never Apotex's intention to encourage physicians or patients to use the generic BIS once-daily. (Tr. at 32). She stated that she never viewed the downward titration language included in the Apotex label (as copied from the AstraZeneca label) as problematic language. (Id. at 27). Indeed, she explained that the people at Apotex were not

even aware there was a problem until they were advised by their own counsel that AstraZeneca objected to the inclusion of this language on another generic company's BIS product. (Id. at 27, 37). Ms. Tau testified that when she became aware of the problem, she called the FDA on April 6, 2008, to propose various labeling alternatives that might alleviate AstraZeneca's concerns.[1] (Id.). She stated that she did so despite her belief that FDA would not accept the proposals:

> we've never been – in any of our previous experiences, been successful in changing any labeling language that we want to initiate, FDA can tell us to change language but we've not been successful in changing any language, and I knew that the chance of making a proposal to FDA on revising any language would not be – would not be – would not have potential or be feasible...

(Tr. at 27).

As Ms. Tau expected, all of her proposals were rejected by the FDA.[2] (Id. at 29-31). After two phone conversations with the FDA in which her proposals were declined, Ms. Tau decided not to pursue the proposals (or other amendments) any further as she believed doing so would be futile. (Id. at 34-35). As she

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[1] She also testified that once she became aware of the issue, she was directed by the FDA to read the FDA's November 18, 2008, response to AstraZeneca's citizen petition (referred to as the "FDA Letter" in the Court's May 14, 2009, Opinion).

[2] Specifically, she proposed three labeling amendments to the FDA: 1) add "twice-daily" to the downward titration statement; 2) remove the downward titration statements; and 3) add language to the effect that "this labeling is not approved for use for less than twice-daily..." (Tr. at 28-31).

explained,

> [w]ith the experience that I've had with the FDA and knowing their, I guess, philosophy around labeling changes and what at least their – at least their philosophy that they do not accept labeling revisions based on the conversation I had and what told to me, I felt that it would have been – wouldn't – it wouldn't have been of any value to take it – pursue it any further. They had indicated that they would no longer – they wouldn't consider any revisions.

(Id. at 57-58).

On cross-examination, Ms. Tau testified that although she knows there are avenues for appealing the FDA's decisions, see, e.g., 21 C.F.R. §§ 314.102(e), 314.103(c)(2), she is not fully aware of all of the procedures because she has never had to utilize them in any ANDA application. (Id. at 37, 40). As to the issue of suitability petitions, Ms. Tau testified that a suitability petition is not intended for making changes to a label's instructions; rather, its purpose is to allow differences in four particular aspects of a drug itself, namely, the active ingredient, route of administration, dosage form, and strength. (Id. at 7-11, 14; see also FDA Rules and Regulations, 57 FR 17950 at III. 20 ("[l]abeling differences, therefore, are not proper subjects for a suitability petition"). Because all of these aspects in Apotex's generic BIS were identical to those in AstraZeneca's PULMICORT RESPULES, Ms. Tau stated that "there was no need to file a suitability petition ... we have the same active ingredient, we have the same route of administration, the

same dosage form and the same strengths that the references to Pulmicort has." (Tr. at 11). However, she did admit that if Apotex had wanted to pursue a different strength – for example, a 0.125 mg/2mL dose for twice-daily administration - it could have done so by filing a suitability petition. (Id. at 53). This it did not do. (Id.). Moreover, as Ms. Tau testified, Apotex did not file a 505(b)(2) application to seek approval to produce this lower strength dose or any other alternatives. (Id. at 55). She explained that there was no reason to file either application with the FDA because Apotex's ANDA application "met all the requirements of an ANDA in meeting the same conditions of use, same active ingredients, same dosage form, same strength and same route of administration..." (Id. at 59).

With the benefit of Ms. Tau's testimony and the exhibits introduced at the hearing, which document the communications between Apotex and the FDA regarding the Apotex labeling, the Court is now able to make a more informed decision on the issue of intent. The evidence presented during the May 20, 2009, hearing shows that Apotex was aware of and certainly concerned about the potential infringement problem posed by its label such that it attempted to cure the problem by proposing labeling alternatives to the FDA. Apotex's own counsel advised Ms. Tau at the beginning of the ANDA application process to include additional twice-daily language on the label. Similarly, upon

learning from Apotex's counsel that the downward titration language was problematic for AstraZeneca, Ms. Tau attempted to resolve the issue by phoning the FDA with specific proposals for a non-infringing label. When the FDA unsurprisingly rejected these proposals, Apotex decided to press forward with its label anyway. Apotex did so despite the fact that the label contained language that Apotex knew to be problematic and, by its own conduct, attempted to remedy, albeit unsuccessfully. In this Court's view, this conduct shows an intent to induce infringement.

The Court recognizes that this conclusion may seem to turn Apotex's intent on its head - after all, Apotex did initially attempt to find alternative non-infringing language for its label. However, even though Apotex's efforts to develop alternative labeling may show that it did not want to induce infringement (and certainly did not want to wage a patent litigation), the fact remains that the labeling Apotex ultimately submitted for ANDA approval does encourage infringement, as the Court has already found. Thus, whatever "good" intent Apotex may have shown in trying to work around the infringement issue was overcome when Apotex moved forward with an infringing label.

Certainly, the patent laws and FDA regulations can collide – compliance with FDA regulations may lead to infringement and production of a non-infringing product may be unsafe. However,

perhaps the two can be reconciled. It seems to this Court that, at a minimum, a party should be required to attempt reconciliation by exhausting all regulatory avenues available. This would ensure that every effort has been made to achieve the objectives of both the patent laws and the FDA regulations - i.e., promote innovation and maintain safety.

Here, although Apotex initially did attempt to find a solution, the record shows that there was more that Apotex could have done to pursue a non-infringing label. Although Ms. Tau credibly testified that she believed that any efforts to argue with the FDA would be futile, AstraZeneca showed that there were indeed other options that Apotex could have pursued if it was really intending not to induce infringement. Apotex could have formally appealed the FDA's decision using one of several procedural avenues available, as pointed out during the hearing. Additionally, and perhaps more importantly, Apotex could have filed a suitability petition or 505(b)(2) application to seek approval for production of a 0.125 mg/2mL strength.[3] Whether or not these efforts would have been successful is a different question. If Apotex had done everything it could have done to dispute the FDA's decision and was still unable to create a label

[3] Indeed, at the hearing, counsel for AstraZeneca admitted that if there were a 0.125 mg/2mL strength dose available with an indication to administer twice-daily, the downward titration language would not teach an infringing use. (Tr. at 66).

that both complied with the FDA requirements and respected AstraZeneca's patent, the decision would be an even more difficult one and, indeed, may yield a different result. However, that issue is not before this Court.

Finally, the Court understands that Apotex does not have an affirmative obligation to protect AstraZeneca's patent rights. However, in the context of analyzing specific intent to induce infringement, there is a very fine line between conduct that affirmatively protects a patent and conduct that shows no intent to infringe a patent. In this Court's view, notwithstanding its negotiations with the FDA, Apotex did not come near this line.

Based on the above analysis, the Court finds that AstraZeneca has made a sufficient showing that Apotex had the requisite specific intent to infringe. Combining this determination with the other findings set forth in the Court's prior Opinion, the Court finds that AstraZeneca has made a sufficient showing for the issuance of a preliminary injunction. AstraZeneca has shown that they will likely succeed on the merits at trial; that they face a risk of irreparable harm if the injunction does not issue; that the balance of hardships clearly weighs in its favor; and that the public interest factor does not militate in favor of either side. Having considered these four factors, this Court finds that a preliminary injunction is warranted in this case. An appropriate order shall issue this

date.

Date: May 22, 2009

s/Renée Marie Bumb
RENÉE MARIE BUMB
United States District Judge